given in the Rajya Sabha on the 19th March, 1986 and state what methods are being adopted to provide the information regarding the side effect, dosages, and precautions to be adopted for a particular medicine in the absence of a mandatory provision in the Drugs and Cosmetics Rules to insert information package on medicines which are being makreted by various companies?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): In the case of New drugs, literature and package inserts containing various aspects of toxicity and therapeutic claims are examined and approved by the Drugs Controller (India) prior to their promotion in the medical professional circle. In cases of other drugs manufacturers are free to disseminate information through professional channels such as general brouchers, package inserts.

Harmful effect of Orabolin tablets/drops

171. SHRIMATI MAIMOONA SULTAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to Unstarred Question No. 2376 answered on 19th March, 1986 in Rajya Sabha and state:

(a) whether it is a fact that Orabolin-tablets and Drops are being promoted in our country for normal growth of children and optimal weight;

(b) whether it is also a fact that there are reports in the world about harmful effects of this product;

(c) whether it is also a fact that the effect of use of this product is irreversible; and

(d) if so, what is Government's reaction thereon?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) Orabolin tablets and Drops, being marketed in the country by M/s. Infar (India) Ltd., Calcutta, are being used for conditions of debility weight loss, burns and cases of anorexia after major surgery.

(b) to (d) The use of anabolic steroids may cause side effect like irreversible masculine effects in girls and stunting of growth in children. Medical experts consulted in the matter had opined in favour of continued marketing of anabolic steroids as these have a specific role in the management of chronic debilitating diseases particularly in elderly patients where causal and dietary measures prove in-adequate to correct defects in protein metabolism. However, based on the recommendations made by the medical experts the manufacture and sale of combinations of anabolic steroids with other drugs has been prohibited by the Government.

D-propoxphene combination with other drugs

172. SHRIMATI MAIMOONA SULTAN:

DR. JOSEPH LEON D'SOUZA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to reply to Unstarred Question 352 given in the Rajya Sabha on 19th March, 1986 in Rajya Sabha and state:

(a) whether it is a fact that combination of D-Propoxphene is being marketed in the country with Lorazepam, Onzepam, and Diazepam;

(b) if so, the names of the drug companies which are marketing such combinations;

(c) what were the considerations on which combination of D-Propoxpherne was allowed with each of these drugs;

(d) whether it is a fact that such combinations are no being marketed anywhere else in the world; and

(e) if so, what are the reasons for allowing marketing of these drugs in India?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) In so far as this Ministry is aware only combi-

nations of D-Propoxyphene with diazepam are marketed in the country.

(b) As per information available with this Ministry the following firms are marketing the combinations of D-Propoxyphene with diazepam:

1. M/s. Wockhardt Pvt. Ltd., Bombay.

2. M/s. Ranbaxy Laboratories Ltd., New Delhi.

3. M/s. Micro Laboratories, Madras.

4. M|s. Vilco Laboratories Pvt. Ltd., Bombay.

5. M/s. Jagson Pal New Delhi.

6. M|s. Wallace Laboratories, Panjim Goa.

(c) and (e) As licences for the manufacture and sale of the formulations are granted by the State Drug Control Authorities, these combinations have been licensed to be manufactured and marketed by the respective State Drug Control Authorities in consultation with their experts.

(d) To the best of our knowledge combination of D-Propoxyphene with Diazepam are not marketed in developed countries.

Banning of harmful drugs

173. DR. JOSEPH LEON D'SOUZA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to reply to Starred Question 352 given in the Rajya Sabha on 19th March, 1986 and state:

(a) whether fixed dose combination of D-Propoxyphene with certain drugs other than paracetamol have been prohibited for sale in India;

(b) whether these combinations fall in any of the pharmacopies of the world;

(c) what are the names of the drugs which have been prohibited for manufacture and sale in the country;

(d) whether it is a fact that these drugs are being manufactured and marketed in the country; and

(e) if so, what are the reasons therefor?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) No ,Sir.

(b) Combinations of D-Propoxyphene with certain drugs other than paracetamol are official in USP XXI-Edition.

(c) The information is given in the statement attached. (*See below*).

(d) and e) Some of the manufacturers marketing certain formulations of these 26 banned drugs have gone in appeal and have obtained stay orders from various courts.

Statement

1. Amidopyrine.

2. Fixed dose combinations of Vitamins with anti-inflamatory agents and tranquillisers.

3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.

4. Fixed dose combinations of Strychnine and Caffeine in Tonics.

5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.

6. Fixed dose combinations of Iron with Strychnine, Arasanic and Yohimbine.

7. Fixed dose combinations of Sodium Bromide/Chloral hydrate with other drugs.

8. Phenecatin.

9. Fixed dose combinations of antihistaminics with anti-diarrhoeals.

10. Fixed dose combinations of Penicillin with Sulphonamides.

11. Fixed dose combinations of Vitamins with Analgesics.